7 DE Admin Code 1134: Emission Banking and Trading Program

Section 1.0: Program Overview (Effective 10/06/1997)
Section 2.0: Definitions (Effective 10/06/1997)
Section 3.0: Applicability (Effective 10/06/1997)
Section 4.0: Generating an Emission Reduction (Effective 10/06/1997)
Section 5.0: Application for Certification of an Emission Reduction as an ERC (Effective 10/06/1997)
Section 6.0: Source Baseline (Effective 10/06/1997)
Section 7.0: Post-Reduction Emission rate (Effective 10/06/1997)
Section 8.0: Certification of an Emission Reduction (Effective 10/06/1997)
Section 9.0: Trading and Use of ERCs (Effective 10/06/1997)
Section 10.0: Record Keeping Requirements (Effective 10/06/1997)
Section 11.0: ERC Banking System (Effective 10/06/1997)
Section 12.0: Fees (Effective 10/06/1997)
Section 13.0: Enforcement (Effective 10/06/1997)
Section 14.0: Program Evaluation and Individual Audits (Effective 10/06/1997)

7 DE Admin. Code 1135: Conformity of General Federal Actions to the State Implementation Plans

Section 1.0: Purpose (Effective 08/14/1996)
Section 2.0: Definitions (Effective 08/14/1996)
Section 3.0: Applicability (Effective 08/14/1996)
Section 4.0: Conformity Analysis (Effective 08/14/1996)
Section 5.0: Reporting Requirements (Effective 08/14/1996)
Section 6.0: Public Participation and Consultation (Effective 08/14/1996)
Section 7.0: Frequency of Conformity Determinations (Effective 08/14/1996)
Section 8.0: Criteria for Determining Conformity of General Federal Actions (Effective 08/14/1996)
Section 9.0: Procedures for Conformity Determinations of General Federal Actions (Effective 08/14/1996)
Section 10.0: Mitigation of Air Quality Impacts (Effective 08/14/1996)
Section 11.0: Savings Provisions (Effective 08/14/1996)

7 DE Admin. Code 1139: Nitrogen Oxides (NO_X) Budget Trading Program

Section 1.0: Purpose (Effective 12/11/2000)
Section 2.0: Emission Limitation (Effective 12/11/2000)
Section 3.0: Applicability (Effective 12/11/2000)
Section 4.0: Definitions (Effective 12/11/2000)
Section 5.0: General Provisions (Effective 12/11/2000)
Section 6.0: NO_X Authorized Account Representative for NO_X Budget Sources (Effective 12/11/2000)
Section 7.0: Permits (Effective 12/11/2000)
Section 8.0: Monitoring and Reporting (Effective 12/11/2000)
Section 9.0: NATS (Effective 12/11/2000)
Section 10.0: NO_X Allowance Transfers (Effective 12/11/2000)
Section 11.0: Compliance Certification (Effective 12/11/2000)
Section 12.0: End-of-Season Reconciliation (Effective 12/11/2000)
Section 13.0: Failure to Meet Compliance Requirements (Effective 12/11/2000)
Section 14.0: Individual Units Opt-Ins (Effective 12/11/2000)
Section 15.0: General Accounts (Effective 12/11/2000)
Appendix A: Allowance Allocations to NO_X Budget Units under 3.1.1.1 and 3.1.1.2 of DE Admin. Code 1139 (Effective 02/11/2000)
Appendix B: 7 DE Admin. Code 1137—7 DE Admin. Code 1139 Program Transition (Effective 02/11/2000)

7 DE Admin. Code 1140: Delaware's National Low Emission Vehicle (NLEV) Regulation

Section 1.0: Applicability (Effective 09/11/1999)
Section 2.0: Definitions (Effective 09/11/1999)
Section 3.0: Program Participation (Effective 09/11/1999)

7 DE Admin. Code 1142: Specific Emission Control Requirements

Section 1.0: Control of NO_X Emissions from Industrial Boilers (Effective 12/12/2001)

7 DE Admin. Code 1143: Heavy Duty Diesel Engine Standards

Section 1.0: On Road Heavy Duty Diesel Requirements for Model Years 2005 and 2006 (Effective 02/11/2005)
Section 2.0: On Road Heavy Duty Diesel Requirements for Model Year 2007 and Later (Effective 02/11/2005)

7 DE Admin. Code 1144: Control of Stationary Generator Emissions [1]

Section 1.0: General (Effective 01/11/2006)
Section 2.0: Definitions (Effective 01/11/2006)
Section 3.0: Emissions (Effective 01/11/2006)
Section 4.0: Operating Requirements (Effective 01/11/2006)
Section 5.0: Fuel Requirements (Effective 01/11/2006)
Section 7.0: Emissions Certification, Compliance, and Enforcement (Effective 01/11/2006)
Section 8.0: Credit for Concurrent Emissions Reductions (Effective 01/11/2006)
Section 9.0: DVFA Member Companies (Effective 01/11/2006)

7 DE Admin. Code 1145: Excessive Idling of Heavy Duty Vehicles

Section 1.0: Applicability (Effective 04/11/2005)
Section 2.0: Definitions (Effective 04/11/2005)
Section 3.0: Severability (Effective 04/11/2005)
Section 4.0: Operational Requirements for Heavy Duty Motor Vehicles (Effective 04/11/2005)
Section 5.0: Exemptions (Effective 04/11/2005)
Section 6.0: Enforcement and Penalty (Effective 04/11/2005)

7 DE Admin. Code 1146: Electric Generating Unit (EGU) Multi-Pollutant Regulation

Section 1.0: Preamble (Effective 12/11/2006)
Section 2.0: Applicability (Effective 12/11/2006)
Section 3.0: Definitions (Effective 12/11/2006)
Section 4.0: NO_X Emissions Limitations (Effective 12/11/2006)
Section 5.0: SO_2 Emissions Limitations (Effective 12/11/2006)
Section 6.0: Mercury Emissions Limitations (Effective 12/11/2006)
Section 7.0: Recordkeeping and Reporting (Effective 12/11/2006)
Section 8.0: Compliance Plan (Effective 12/11/2006)
Section 9.0: Penalties (Effective 12/11/2006)

7 DE Admin. Code 1148: Control of Stationary Combustion Turbine Electric Generating Unit Emissions

Section 1.0: Purpose (Effective 07/11/2007)
Section 2.0: Applicability (Effective 07/11/2007)
Section 3.0: Definitions (Effective 07/11/2007)
Section 4.0: NO_X Emissions Limitations (Effective 07/11/2007)
Section 5.0: Monitoring and Reporting (Effective 07/11/2007)
Section 6.0: Recordkeeping (Effective 07/11/2007)
Section 7.0: Penalties (Effective 07/11/2007)
(2) [Reserved]

* * * * *

[FR Doc. E9–19324 Filed 8–11–09; 8:45 am]

BILLING CODE 6560–50–P

[1] All sections for 7 DE Admin. Code 1144: Control of Stationary Generator Emissions shall be incorporated by reference into 40 CFR part 55 except for all references to Carbon Dioxide (CO_2).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0041; FRL–8430–5]

Sodium Lauryl Sulfate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of sodium lauryl sulfate (CAS Reg. No. 151–21–3) when used as a component of food contact sanitizing solutions applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 350 parts per million (ppm). ETI H2O submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a

tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium lauryl sulfate.

DATES: This regulation is effective August 12, 2009. Objections and requests for hearings must be received on or before October 13, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0041. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e-mail address: *leifer.kerry@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0041 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 13, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0041, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background

In the **Federal Register** of February 6, 2008 (73 FR 6964) (FRL–8350–9), EPA issued a notice pursuant to section 408 (d)(3) of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 7F7179) by ETI H2O, 1725 Gillespie Way, El Cajon, CA 92020. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of sodium lauryl sulfate (CAS Reg. No. 151–21–3) as a component of food contact sanitizing solutions applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils which increases the maximum level in the end-use concentration from 3 ppm to 350 ppm. That notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene ploymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for exemption from the requirement of a tolerance for residues of sodium lauryl sulfate when used as a component of food contact sanitizing solutions applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 350 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicology database is adequate to support the use of sodium lauryl sulfate as an inert ingredient in pesticide formulations as well as its use as a component of food contact sanitizing solutions.

Sodium lauryl sulfate has low acute oral and dermal toxicity but is irritating to the skin and eye at high doses. Sodium lauryl sulfate is not a skin sensitizer. Sodium lauryl sulfate was negative in tests for genotoxicity. The repeated dose toxicity data on alkyl sulfates including sodium lauryl sulfate demonstrate effects consistent with surfactant-mediated irritant effects. The common target organs of toxicity following repeated-dose oral exposure were the forestomach in gavage studies, and the liver and kidneys in dietary studies. No evidence of neurotoxicity was observed in any of the available studies. Chronic toxicity data on sodium lauryl sulfate is available in limited, summary form. A developmental toxicity study with sodium lauryl sulfate in rats, rabbits and mice demonstrated developmental toxicity at maternally toxic doses at a dose level of 600 milligrams/kilogram/day (mg/kg/day). A 2-generation reproductive toxicity study conducted with a related chemical, α-alkyl (C_{12}) olefin sulfonate, showed no treatment-related adverse reproductive effects.

Specific information on the studies received and the nature of the adverse effects caused by sodium lauryl sulfate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document *Sodium Lauryl Sulfate. Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations*. pages 6–9 in docket ID number EPA–HQ–OPP–2008–0041.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for sodium lauryl sulfate used for human risk assessment is shown in the following Table.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SODIUM LAURYL SULFATE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	An endpoint attributable to a single exposure was not seen in the database; therefore, a point of departure was not selected.		

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SODIUM LAURYL SULFATE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Chronic dietary (all populations)	NOAEL= 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 1 mg/kg/day cPAD = 1 mg/kg/day	28-Day oral (gavage) toxicity study in rats LOAEL = 200 mg/kg/day,based on decreased body weight gain
Incidental oral, dermal and inhalation (short-term and intermediate-term)	NOAEL= 100 mg/kg/day Dermal absorption of 1% inhalation exposure is assumed to be equivalent to oral exposure UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential/occupational LOC for MOE = 100	28-Day oral (gavage) toxicity study in rats LOAEL = 200 mg/kg/day, based on decreased body weight gain
Cancer (oral, dermal, inhalation)	Classification: Based on limted data sodium lauryl sulfate is not expected to be carcinogenic.		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a=acute, c=chronic). FQPA SF = FQPA Safety Factor. RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sodium lauryl sulfate, EPA considered exposure under the petitioned-for exemption from the requirement of a tolerance. EPA assessed dietary exposures from sodium lauryl sulfate in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of sodium lauryl sulfate were seen in the toxicity databases; therefore, an acute dietary exposure assessment for sodium lauryl sulfate is not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for sodium lauryl sulfate. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is found at *http://www.regulations.gov* in the document *Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

In addition to dietary exposures resulting from use of sodium lauryl sulfate as an inert ingredient in pesticide formulation application to crops, a conservative dietary exposure estimate of residues of sodium lauryl sulfate in food as a result of its use as a component in food contact sanitizing solution was also performed. This estimate also utilizes conservative assumptions related to the amount of residues that can be transferred to foods as a result of use of food contact sanitizing products.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredients in agricultural products is generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather, there is generally a combination of different inert ingredients used thereby further reducing the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating the level of inert residue that could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data show that tolerance level residues

are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

iii. *Cancer*. There is no evidence that sodium lauryl sulfate is carcinogenic. While the full study reports are not available, summary data on two carcinogenicity studies with sodium (C_{12}-C_{15}) alkyl sulfate show no increase in tumor incidence, nor any impact on tumor type at levels up to up to 1.5% highest dose tested (HDT) in the diet.

Since the Agency has not identified any concerns for carcinogenicity relating to sodium lauryl sulfate, a cancer dietary exposure assessment was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for sodium lauryl sulfate. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for *sodium lauryl sulfate* in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of sodium lauryl sulfate. Further information regarding EPA drinking water models used in the pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

A screening level drinking water analysis, based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) was performed to calculate the estimated drinking water concentrations (EDWCs) of sodium lauryl sulfate. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of sodium lauryl sulfate were conducted. Modeled acute drinking water values ranged from 0.001 parts per billion (ppb) to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking water analysis can be found at *http://www.regulations.gov* in the document *Sodium Lauryl Sulfate. Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredients in Pesticide Formulations,* pages 10 and 25–27 in docket ID number EPA–HQ–OPP–2008–0041.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for sodium lauryl sulfate, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for chronic dietary risk assessments for the parent compounds and for the metabolites of concern. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Sodium lauryl sulfate may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in both indoor and outdoor residential exposures. A screening level residential exposure and risk assessment was completed for products containing sodium lauryl sulfate. The Agency conducted an assessment to represent worst-case residential exposure by assessing sodium lauryl sulfate in pesticide formulations resulting in the highest residential exposures, including both residential handler exposures and residential post-application exposures. Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the document *Joint Insert Task Force (JITF) Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations*, in docket ID number EPA–HQ–OPP–2008–0710.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has not found sodium lauryl sulfate to share a common mechanism of toxicity with any other substances, and sodium lauryl sulfate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sodium lauryl sulfate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for sodium lauryl sulfate includes a prenatal developmental toxicity study in rats, rabbits, and mice as well as a 2-generation reproduction toxicity study in rats on a closely related compound. There was no evidence of increased quantitative or qualitative susceptibility following *in utero* exposure of rats, rabbits or mice in the developmental toxicity study and no evidence of increased quantitative or qualitative susceptibility of offspring in the reproduction study. Developmental toxicity was not observed in the developmental toxicity study at doses below that which maternal toxicity was also observed. In the reproduction study, no offspring or maternal toxicity was observed at the highest dose tested (HDT) of 285 mg/kg/day. There is no evidence of neurotoxicity in the toxicity database for sodium lauryl sulfate.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for sodium lauryl sulfate is considered adequate for assessing the risks to infants and children (the available studies are described in Unit IV.D.2.).

ii. No evidence of quantitative or qualitative increased susceptibility was demonstrated in the offspring in a

developmental toxicity study in rats, rabbits, and mice following *in utero* and prenatal exposure or in young rats in the 2-generation reproduction study.

iii. There is no indication that sodium lauryl sulfate is a neurotoxic chemical and thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. The Agency has concluded that an additional uncertainty factor is not needed for the use of a subchronic study for a chronic exposure assessment as reported NOAELs in two chronic rat studies were at the same levels as the POD derived from a subchronic toxicity study.

v. There are no residual uncertainties identified in the exposure databases. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children. The food exposure assessments are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and the assumption that for all crops, 100% of the crop is treated as well as similarly conservative assumptions related to the transfer of residues of sodium lauryl sulfate into food from its use in food contact sanitizing solutions. EPA also made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to sodium lauryl sulfate in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by sodium lauryl sulfate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. There was no hazard attributable to a single exposure seen in the toxicity database for sodium lauryl sulfate. Therefore, sodium lauryl sulfate is not expected to pose an acute risk.

2. *Chronic risk*. A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure, the chronic dietary exposure from food and water to sodium lauryl sulfate is 19% of the cPAD for the U.S. population and 67% of the cPAD for children 1 to 2 years old, the most highly exposed population subgroup.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Sodium lauryl sulfate is used in pesticide products that are currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to sodium lauryl sulfate. Using the exposure assumptions described in this unit, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in aggregate MOEs of 500, for both adult males and females, respectively. Adult residential exposure combines high end dermal and inhalation handler indoor and outdoor exposure with a high end post application dermal exposure. EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 147 for children. Children's residential exposure combines outdoor and indoor dermal and hand-to-mouth exposures. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Sodium lauryl sulfate is used in products currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to sodium lauryl sulfate. Using the exposure assumptions described in this unit, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 660 for both adult males and females, respectively. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 148 for children. Children's residential exposure combines outdoor and indoor dermal and hand-to-mouth exposures. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. The Agency has not identified any concerns for carcinogenicity relating to sodium lauryl sulfate.

6. *Determination of safety*. Based on these risk assessments and the limitation imposed in the exemption, EPA concludes that, with respect to the exemption, there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to residues of sodium lauryl sulfate under reasonably foreseeable circumstances.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

The Agency is not aware of any country requiring a tolerance for sodium lauryl sulfate nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of sodium lauryl sulfate as a component of food contact sanitizing solutions applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 350 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemtpion from the requirement of a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has

exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 6, 2009.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In §180.940(a), the table is amended by revising the following entry to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide chemical	CAS Reg. No.	Limits
* * * * *		* *
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate).	151–21–3	When ready for use, the end-use concentration is not to exceed 350 ppm.
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0129; FRL–8426–3]

Carbon Black; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of carbon black (CAS Reg. No. 1333–86–4) under 40 CFR 180.920 when used as an inert ingredient (colorant) in pesticide formulations applied to seeds used to grow agricultural and horticultural crops. Becker Underwood, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of carbon black.

DATES: This regulation is effective August 12, 2009. Objections and requests for hearings must be received on or before October 13, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0129. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as